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| 09/771,569 | 01/30/2001 | James P. Clarkin | P 00277116 | 1204 |
| 909 | 7590 | 04/07/2005 | EXAMINER | |
| PILLSBURY WINTHROP SHAW PITTMAN, LLP | | | TRAN, MY CHAU T | |
| P.O. BOX 10500 | | | ART UNIT | |
| MCLEAN, VA 22102 | | | PAPER NUMBER | |
| | | | 1639 | |

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,569

Applicant(s)

CLARKIN ET AL.

Examiner

MY-CHAU T. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 2,16,18,32 and 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,17,19-31,33-36 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 03/09/05 is acknowledged and entered. Claim 42 has been canceled. Claim 1 has been amended. It is noted that claim 43 has an incorrect status identifier, i.e. the identifier should be 'previously presented' not 'new'.
2. Claim 1 was amended by the amendment filed on 2/10/2004, and 8/19/2003.
3. Claims 3-7 were amended, and claims 38-41 were added by the amendment filed on 11/20/2002.
4. Claims 1-41, and 43 are pending.

Response to Amendment

5. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. This action is a Non-Final Office action because upon further reconsideration of the cited prior arts of Anderson et al. (US Patent 5,922,591), Beattie (US Patent 5,843,767), and Jansen (US Patent 5,173,097) the newly added limitation of "*an initial substrate with at least two preformed*" would not overcome the cited prior arts. The examiner apologizes for any inconvenient that this may have cause.

Election/Restrictions

6. Claims 2, and 37 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to ***nonelected inventions***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/20/2003. However, it is noted that claims 6 and 7 were amended to depend on claim 1 or 3 and should have been rejoined with the elected invention. Thus, claim 6 and 7 is rejoined with the elected invention.

1. Applicant has elected the following species for the elected invention (Claims 1, 3-36, and 38-43):

- a. Species A/F (channel cross sectional area): 0.0001 mm^2 to 1 mm^2 .
- b. Species B/G (channel length): 1 mm to 1 km
- c. Species C (substrate): glass
- d. Species D (exterior coating): polyimide
- e. Species E (interior coating): hydrophobic bonded phases
- f. Species H (endcap substrate): glass

2. Claims 16, 18, 32, and 38-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to ***nonelected species***, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/10/03.

Priority

7. This application claims priority to a provisional application 60/254,881 filed 12/13/2000.
8. Claims 1, 3-15, 17, 19-31, 33-36, and 43 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 6, 11-13, and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jansen (US Patent 5,173,097).

The instant claimed invention recites a device for analyzing a plurality of sample components. The device comprises a drawn substrate having a length and at least two drawn channels formed therethrough, said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough; the drawn channels extending in a direction parallel to the length, and the substrate including inlets and outlets in cooperating relation with the drawn channels.

The instant invention is written as a product-by-process claim. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. Thus as claimed, the product limitations is that the device comprises a) a substrate, and b) two channels in parallel with an inlets and outlets. The process limitation is that the substrate and two channels are drawn from an initial substrate with two preformed channels, i.e. drawn process wherein the substrate and two channels are stretched along its length and reducing the cross sectional area (see specification pg. 6, lines 16-18).

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Jansen discloses a device (see e.g. Abstract; col. 2, lines 26-43; col. 3, lines 11-17; figures 2(a) and 3(b)). The device comprises a substrate of optical waveguide and channels that extend in a direction parallel to the length (see e.g. figure 3(b); col. 3, lines 22-35; col. 7, lines 44-60). The drawn substrate include an inlets and outlets (see e.g. figure 13). The device is made by a process that elongates the product and reduced the cross-section of the device (see e.g. fig. 1; col. 2, lines 38-40; col. 5, line 63 thru col. 6, line 16). The device is use in an endoscope system (refers to instant claim 6) (see e.g. col. 4, lines 26-33; col. 9, lines 36-51). Therefore, the drawn substrate of Jansen anticipates the presently claimed invention.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough*". The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Jansen (US Patent 5,173,097). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Thus the device of Jansen would still anticipates the presently claimed device since it meets all the structural limitation of the claimed device that is substrate having two channels formed therein wherein the channels comprise of inlets, outlets, spaced apart, and are in a parallel direction.

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11. Claims 1, 3-10, 14-15, 17, 20-31, 33-36, and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beattie (US Patent 5,843,767).

The instant claimed invention recites a device for analyzing a plurality of sample components. The device comprises a drawn substrate having a length and at least two drawn channels formed therethrough, said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough; the drawn channels extending in a direction parallel to the length, and the substrate including inlets and outlets in cooperating relation with the drawn channels.

The instant invention is written as a product-by-process claim. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. Thus as claimed, the product limitations is that the device comprises a) a substrate, and b) two channels in parallel with an inlets and outlets. The process limitation is that the substrate and two channels are drawn from an initial substrate with two preformed channels, i.e. drawn process wherein the substrate and two channels are stretched along its length and reducing the cross sectional area (see specification pg. 6, lines 16-18).

Beattie discloses a genosensors (see e.g. Abstract; col. 1, lines 29-39; col. 5, line 27 to col. 6, lines 13; col. 9, lines 60-67; fig. 1B and 3). The device comprise of a nanochannel glass array (i.e. substrate having two channels formed therein wherein the channels comprise of inlets, outlets, spaced apart, and are in a parallel direction) (see e.g. col. 5, line 27 to col. 6, lines 13; col. 9, lines 60-67; fig. 1B and 3). The array comprise of inserting a cylindrical glass rod into an inert glass tube (see e.g. col. 9, lines 62-67) (channel in parallel direction). The pair is drawn under a vacuum to reduce the overall cross-sectional area (see e.g. col. 9, line 67 to col. 10, line 1). The length of the channels is about 0.1 to 1.0 mm with a diameter of 300 nm (0.07 mm²) and a center-to-center spacing of about 750 nm (see e.g. col. 10, lines 10-31). The genosensors is

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utilized in system such as electronic detection system or DNA chip (see e.g. col. 1, lines 35-39; col. 2, line 66 thru col. 4, line 2). Therefore, the device of Beattie anticipates the presently claimed inventions.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough*". The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Jansen (US Patent 5,173,097). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Thus the device of Beattie would still anticipate the presently claimed device since it meets all the structural limitation of the claimed device that is substrate having two channels formed therein wherein the channels comprise of inlets, outlets, spaced apart, and are in a parallel direction.

12. Claims 1, 3-4, 7-10, 14-15, 19, 21, 26, 28-29, 31, 34-36, and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson et al. (US Patent 5,922,591).

The instant claimed invention recites a device for analyzing a plurality of sample components. The device comprises a drawn substrate having a length and at least two

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drawn channels formed therethrough, said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough; the drawn channels extending in a direction parallel to the length, and the substrate including inlets and outlets in cooperating relation with the drawn channels.

The instant invention is written as a product-by-process claim. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. Thus as claimed, the product limitations is that the device comprises a) a substrate, and b) two channels in parallel with an inlets and outlets. The process limitation is that the substrate and two channels are drawn from an initial substrate with two preformed channels, i.e. drawn process wherein the substrate and two channels are stretched along its length and reducing the cross sectional area (see specification pg. 6, lines 16-18).

Anderson et al. disclose a device (see e.g. Abstract; col. 2, lines 20-39; col. 5, lines 13-25). The device utilized in an integrated nucleic acid diagnostic system (see e.g. col. 5, lines 13-15). The device comprises various reaction chambers and fluid passages (channels), which is manufactured onto the surface of the substrate (i.e. substrate having two channels formed therein wherein the channels comprise of inlets, outlets, spaced apart, and are in a parallel direction) (see e.g. col. 17, lines 59-61; fig. 12c; col. 19, lines 29-33). The fluid channels have smaller dimensions relative to the chambers and range about 10 μm wide and 1 μm deep (e.g. a cross sectional area of about 0.1 mm^2) (see e.g. col. 18, lines 30-40) (referring to claim 4). The body of the device (substrate) comprise of glass (referring to claim 15 and 31). The surfaces of the channel may be made more hydrophobic by coating the surface (see e.g. col. 20, lines 33-40) (referring to claim 19). The channel comprise of inlets and outlets valves (see e.g. col. 30, lines 41-50). In figure 12c, the device comprises a plurality of channels, wherein the main channel is ref. # 1252 (col. 30, lines 26-31). The various channels connecting the chambers to the main

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channel are in a parallel direction. The channels comprise of a "bend" that connect two channels together and are spaced apart (fig. 12c). Therefore, the device of Anderson et al. anticipates the presently claimed invention.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough*". The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Jansen (US Patent 5,173,097). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Thus the device of Beattie would still anticipates the presently claimed device since it meets all the structural limitation of the claimed device that is substrate having two channels formed therein wherein the channels comprise of inlets, outlets, spaced apart, and are in a parallel direction.

Response to Arguments

13. Applicant's arguments filed 03/09/2005 have been fully considered but they are not persuasive.

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Applicant amended claim 1 with the limitation of "*said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough*" in order to distinguish the presently claimed invention from the cited prior arts of Jansen (US Patent 5,173,097), Beattie (US Patent 5,843,767), and Anderson et al. (US Patent 5,922,591). However, this process limitation does not distinguish the presently claimed invention from the cited prior arts of Jansen (US Patent 5,173,097), Beattie (US Patent 5,843,767), and Anderson et al. (US Patent 5,922,591) because of the following reasons:

1) The instant claims are written as product-by-process claims. Applicant is directed to MPEP 2113 with regard to the product-by-process claim.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Thus as claimed, the product limitations is that the device comprises a) a substrate, and b) two channels in parallel with an inlets and outlets. These limitations are anticipated by the cited prior arts of Jansen (US Patent 5,173,097), Beattie (US Patent 5,843,767), and Anderson et al. (US Patent 5,922,591) (see above rejection).

2) The process limitation of "*said drawn substrate and at least two drawn channels being drawn from an initial substrate with at least two preformed channels formed therethrough*" does not impart distinctive structural characteristics to the final product that is a device comprising a substrate, and two channels in parallel with an inlets and outlets.

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Thus this process limitation does not distinguish the presently claimed invention from the cited prior arts of Jansen (US Patent 5,173,097), Beattie (US Patent 5,843,767), and Anderson et al. (US Patent 5,922,591), and the rejections of the cited prior arts are reinstated and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
April 1, 2005

BENNETT CELSA
PRIMARY EXAMINER

